DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Emend
Docket No.: 2003E-0418

JUL 24 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,719,147, filed by Merck & Co., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Emend (aprepitant), the human drug product claimed by the patent.

The total length of the regulatory review period for Emend (aprepitant) is 2,513 days. Of this time, 2,332 days occurred during the testing phase and 181 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 10, 1996.

   The applicant claims May 9, 1996, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 10, 1996, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 27, 2002.

   FDA has verified the applicant's claim that the new drug application (NDA) for Emend (aprepitant) (NDA 21-549) was initially submitted on September 27, 2002.

3. The date the application was approved: March 26, 2003.

   FDA has verified the applicant's claim that NDA 21-549 was approved on March 26, 2003.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: J. Eric Thies
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